

Congress of the United States
Washington, DC 20515

May 4, 2018

The Honorable Francis Collins
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Director Collins:

We write in support of the application submitted by Immuno-Mycologics, Inc. (IMMY) for \$2.26 million in Phase I and Phase II funding from the National Institutes of Health's (NIH) Small Business Innovation Research (SBIR) grant program. Securing SBIR grant funding would enable IMMY to clear the regulatory requirements to move enhanced diagnostics for Coccidioidomycosis, more commonly known as Valley Fever, into primary care settings.

As you know, Valley Fever is an infection caused by inhaling the spores of a fungus commonly found in the soil of the American southwest. According to the Centers for Disease Control and Prevention (CDC), there were 11,829 reported cases of Valley Fever in 2016, with the vast majority occurring in California and Arizona. While the scientific community has made important advancements in Valley Fever research in recent years, much remains to be understood about this disease. As a result, Valley Fever continues to be frequently misdiagnosed and there remains a gaping absence of a vaccine and effective medications to treat the disease.

As you may recall from your visit to Bakersfield in 2013 for the Valley Fever Symposium, one of the action items that emerged from that forum was the need to develop better tests for the disease. Currently, diagnosing Valley Fever requires either blood work or CT-scans, both of which take multiple days at a minimum to produce results. IMMY's Coccidioides Total Antibody Lateral Flow Assay (LFA) detects the presence of Valley Fever antibodies in as little as 30 minutes and can rule out suspected cases of Valley Fever. The development of a quick and accurate method to diagnose Valley Fever is an important step forward to help health care providers expedite the diagnostic process, leading to more precise treatment, as well as preventing the unnecessary use of antibiotics.

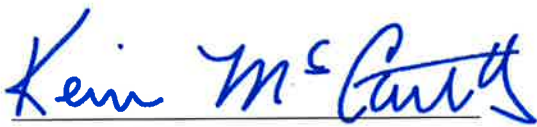
SBIR grant funding will enable IMMY to perform the Food and Drug Administration (FDA) 510k clearance and Clinical Laboratory Improvement Amendment waived studies necessary to move the LFA into primary care settings. The LFA is currently approved by the FDA for use in hospitals and reference laboratories. However, the LFA is not approved for use in physician offices and urgent care clinics, where many patients go when experiencing Valley Fever's flu-like symptoms. IMMY intends to partner with Dr. John Galgiani at the University of Arizona Valley Fever Center for Excellence and Dr. George Thompson at the University of California, Davis to evaluate the LFA in primary care settings throughout participating sites in the endemic regions of California and Arizona.

Additionally, we commend the NIH's efforts in developing the randomized control trial (RCT) to test the efficacy of Fluconazole as an antifungal treatment for Valley Fever. However, as you are likely aware, the RCT has struggled to enroll individuals to participate. While low enrollment can be attributed to a variety of reasons, an accurate and timelier diagnostic tool for Valley Fever would be a critical step forward that could result in more individuals participating in the RCT.

SBIR grant funding will help IMMY clear FDA regulatory requirements to deploy innovative technology to more quickly and accurately diagnose Valley Fever. It is our understanding that this project aligns with SBIR's stated intent: to fund early-stage small businesses that are seeking to commercialize innovative biomedical technologies to improve health and save lives. Again, we support IMMY's application for SBIR grant funding and respectfully ask for your full and fair consideration of their application.

Please do not hesitate to contact us if you have any questions. Thank you for your attention to this important matter.

Sincerely,




KEVIN MCCARTHY
House Majority Leader
Co-Chair, Valley Fever Task Force



DAVID SCHWEIKERT
Member of Congress
Co-Chair, Valley Fever Task Force



STEPHEN KNIGHT
Member of Congress
KYRSTEN SINEMA
Member of Congress
DAVID G. VALADAO
Member of Congress
MARTHA MCSALLY
Member of Congress
PAUL COOK
Member of Congress
CHRIS STEWART
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TOM O'HALLERAN
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JUAN VARGAS
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JIM COSTA
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DEVIN NUNES
Member of Congress

cc:
Dr. Michael Lauer
Director
Office of Extramural Research
National Institutes of Health